UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS Subcategory Case No. 03-10643
THIS DOCUMENT RELATES TO: *The City of New York, et al.* *v.* *Abbott Laboratories, et al.*	Judge Patti B. Saris Magistrate Judge Bowler

PLAINTIFFS' REPLY MEMORANDUM IN FURTHER SUPPORT OF MOTION TO COMPEL DISCOVERY FROM DEFENDANT MERCK & CO., INC.

INTRODUCTION

Merck's continued refusal to produce discovery on at-issue drugs with alleged spreads of greater than 30% is baseless and obstructive. Both CMO #33, which Merck and all other defendants presented to this Court by way of a Joint Motion [Dkt. No. 4690], and the Court's September 28, 2008 Order [Dkt. No. 5605] (attached as "A" hereto) establish unequivocally that plaintiffs are entitled to discovery on drugs with alleged spreads greater than 30%. Plaintiffs have demonstrated their entitlement to discovery on these drugs by setting forth over-30% spreads using the two methods approved by this Court. One is through the use of wholesaler data; the second through the use of Merck's AMPs. *See* Revised Exhibit B-24 to Plaintiffs' First Amended Consolidated Complaint ("Rev. Exhibit B to the FACC") [Dkt. No. 4754]; and Exhibit A to the Declaration of Harris L. Devor in Support of Plaintiffs' Motion to Compel Discovery from Defendant Merck & Co., Inc. (hereinafter referred to as "Devor Decl. Exh. A") [Dkt. No. 6489, Sub-dkt. No. 160]. Indeed, using Merck's own AMPs, plaintiffs have, through their

expert Harris Devor, presented annual over-30% spreads for the Merck drugs/NDCs on which discovery is sought.

Notwithstanding this, Merck refuses to produce data and documents essential to establishing what Merck's real prices are and to presenting this Court with a full and accurate record so that the extent of Merck's' liability for the claims asserted can be established once and for all. Merck simply refuses to accept that plaintiffs have now twice demonstrated, first through the use of wholesaler data and second through the use of Mercks' own AMPs, that there are Merck Drugs and NDCs at issue in this case with spreads that satisfy the 30% discovery screen. Merck's opposition rests on unsupported, fact-intensive and misleading arguments that merely reinforce why discovery is appropriate and must be had. We address each in turn.

ARGUMENT

I. This Court Has Ruled That "Plaintiffs may conduct discovery on any branded drugs that have an AWP to AMP spread of over 30% for the year"[1]

In an effort to distract from the simplicity of the issue before this Court, Merck says that plaintiffs are engaging in "mathematical gymnastics", employing the "device" of AMP to allege spreads and "move the goal post" as to when discovery should be produced. Defendant Merck & Co., Inc.'s Opposition to Plaintiffs' Motion to Compel ("Merck Opp.") at 12 [Dkt. No. 6572, Sub-dkt. No.168]. No gymnastics are involved. There is no "device" and no "goal posts" have been moved. This Court expressly has ruled that plaintiffs are entitled to discovery where the AMP/AWP spread is greater than 30% on an annual basis. September 22, 2008 Order [Dkt. No. 5605] ("A" hereto). That Order provides, plain and simple, that **"Plaintiffs may conduct discovery on any branded drugs that have an AWP to AMP spread of over 30% for the year"** *Id.*. Plaintiffs are merely seeking compliance, by Merck, with that order.

[1] September 22, 2008 Order [Docket No. 5605] ("A" hereto).

Merck acknowledges that AMP may provide a "useful conservative check on plaintiffs' use of wholesaler data". Merck Opp. at 2, ¶ 2 [Dkt. No. 6572, Sub-dkt. No. 168]. There is no dispute. Plaintiffs here seek only production of discovery on those Merck drugs at issue where the AMP/AWP spreads are in excess of 30% on an annual basis, regardless what the spreads were in Exhibit B to plaintiffs' complaint. What then is the basis for Merck's resistance?

Merck argues that, for certain drugs, the AMP/AWP spreads are lower than the AAC/AWP spreads set forth in plaintiffs' complaint. *See* Merck Opp. at 17-18. Agreed and so what. The issue before the Court is a binary one directed only to the scope of discovery. This is not a damages or even liability assessment. This is a discovery issue. This Court has ruled that if the alleged spread, based on wholesaler data or AMP data, is over 30%, plaintiffs get discovery. *See* CMO #33, ¶ 7 [Dkt. No. 4745]. If below 30%, no discovery. *Id.* It is that simple. It matters not, at this stage, if the spread is 1000% or 45% or 31%. Pursuant to the orders of this Court, including CMO #33 that Merck itself subscribed to and requested entry of, once the alleged spread is over 30%, plaintiffs are entitled to discovery. Only through discovery, including the production of sales and transactional data, can Merck's actual prices be determined. Thereafter, on a full record, liability, if any, can be established and damages, if any, can be calculated.

Merck argues that some of the drugs for which plaintiffs are entitled to discovery have relatively low utilization. *See, e.g.,* Merck Opp at 6. The argument reveals Merck's utter insensitivity to the impact of drug costs on the County Medicaid Programs which spent, in fact, over $306 million on these "not worth it" products for the years identified in Exh. A to the Devor Decl. *See* Exh. A to Devor Decl. [Dkt. No. 6489, Sub-dkt. No. 160]. Moreover, neither the

Jointly-Proposed CMO #33 nor the September 2008 order provide that plaintiffs are only entitled to discovery when some expenditure threshold is satisfied.

Merck disregards that the September 2008 Order expressly provides that plaintiffs are entitled to discovery when AMP/AWP spreads exceed 30% ***"for the year"*** (*see* September 2008 Order)**.** In what must be an effort to mislead, Merck instead has its expert instead present a chart demonstrating the "overall" (i.e. 1997-2005 en toto) spreads. *See* Affidavit of Eric M. Gaier, Ph.D., sworn to October 5, 2009 at Figure 3 ("Gaier Aff")(attached as Exhibit 7 to the Declaration of Robert Funkhouser [Dkt.No. 6574-8]. There is no requirement anywhere, nor does Merck cite one, that plaintiffs are only entitled to discovery when spreads exceed 30% for the entire 1997-2005 time period. The September 2008 Order ("A" hereto) requires spreads over 30% "for the year" and, indeed, Judge Saris therein even noted that "it may be better to have ***quarterly*** calculations". *Id.* (emphasis added).

Further misleading the Court in Gaier Affidavit Figure 3, Merck purposefully omits inclusion of Pepcid and Zocor, Why? The County Medicaid Programs spent over $271 million on Zocor and $64 million on Pepcid in the years for which plaintiffs show annual AMP/AWP spreads greater than 30%. *See* Exh. A to Devor Decl. [Dkt. No. 6489, Sub-dkt. No. 160]. Under both CMO #33 and the September 2008 order, plaintiffs are entitled to discovery on these drugs. Even when spreads for these two drugs are considered in the aggregate (i.e. for all of 1997-2005), they exceed 30%. *See* Gaier Aff. Exh. B[2] Of course, Merck's opposition is silent on that point.

[2] For example, Attachment B shows the following: Pepcid 10mg/ml vial (NDC 00006353904) (48.1% overall Devor spread), Pepcid 10mg/ml vial (NDC 00006354114) (37.5% overall Devor spread), Pepcid 10mg/ml vial (NDC 00006354120) (38.9% overall Devor spread), Pepcid 10mg/ml vial (NDC 00006354149) (37.9% overall Devor spread), Zocor 10mg tablet (NDC 00006073531) (35.5% overall Devor spread), Zocor 5mg tablet (NDC 00006072631) (35.9% overall Devor spread), Zocor 5mg tablet (NDC 00006072654) (35.4% overall Devor spread), Zocor 5mg tablet (NDC 00006072682) (35.9% overall Devor spread).

Merck also appears to be arguing the 30% discovery screen set forth in the jointly proposed CMO #33 and the September 2008 order is, in fact, 35%. Merck Opp. at 8 and 18 [Dkt. No. 6572, Sub-dkt. No. 168]. Obviously, there is no support for this. 30% means 30% and even a marginal spread over that expectation (on an annual basis) translates into discovery and, potentially, millions of dollars of unnecessary reimbursement. Merck may not be sensitive to this but Medicaid Payors, who foot the bills, certainly are.

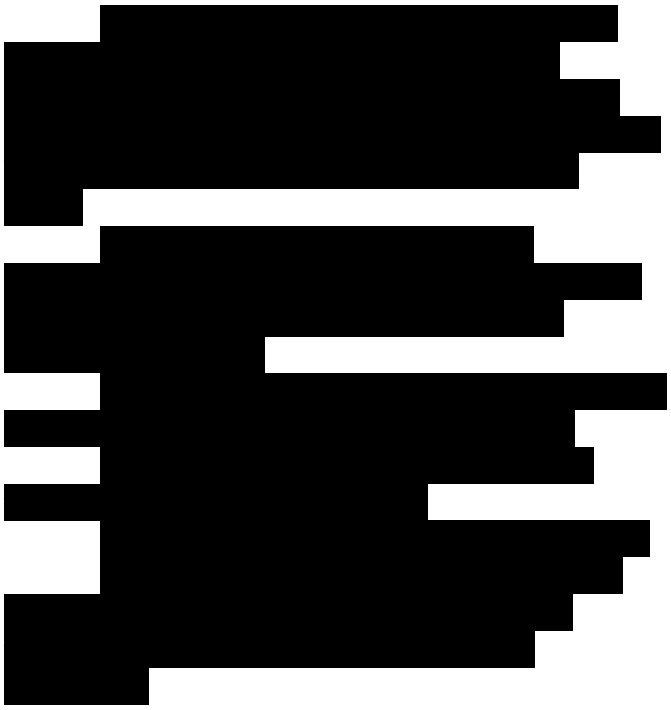
II. Discovery is Needed to Determine What Merck's True Prices are and What Its AMPs Actually Represent

Merck argues that its AMPs cannot be used to satisfy the 30% spread discovery screen because "AMP is derived from manufacturers' sales to wholesalers and necessarily will be less than average or typical prices paid by providers where they acquire drugs from wholesalers, typically by at least 3 to 5%." Merck Opp. at p. 2, ¶ 2 [Dkt. No. 6572, Sub-dkt. No. 168]. Setting aside that Merck is rejecting the use of AMP where its fellow brand defendant Schering (and the Court) accepted, Merck's argument is so flawed as to be utterly meaningless.

First, Merck ignores that when the Court endorsed an AMP/AWP spread over 30% as a "reasonable good faith" basis for discovery, the Court was not making an ultimate finding of liability based on AMP or taking the position that AMP was the same as provider cost. Rather, the Court was designing a reasonable and good faith methodology for determining which drugs should be examined through discovery and which should not. *See also* Point III, *infra*. Only through the production of sales and transactional data will Merck's true provider costs be known and liability, if any, established.

Second, Merck's statement is made with no record support whatsoever and therefore cannot be used as a basis to excuse non-compliance with an unequivocal court order and jointly-proposed CMO #33 or to alter the terms of either.

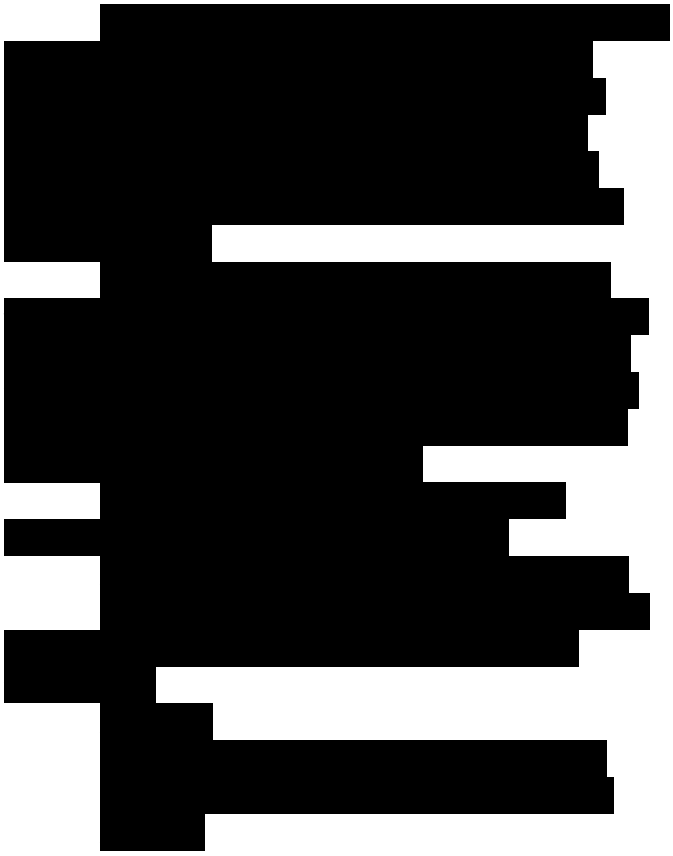
Third, the argument ignores that Merck's AMPs may indeed include Merck's direct sales prices to providers, that such direct sales are typically at prices lower than sales to wholesalers and that such sales would likely have no mark-up associated with them. It also ignores that direct sales to relevant customers may nevertheless pass through the wholesalers for billing purposes. Consider, for example, the following exchange with McKesson 30(b)(6) witness Leslie Morgan concerning direct sales from Merck to Costco:



Deposition of Leslie Morgan (McKesson Corp.) ("Morgan Depo.") dated September 3, 2008 at 121:8-122:4 (attached as Exhibit A to the Declaration Joanne M. Cicala, dated October 23, 2009) ("Cicala Dec."). Does Merck include such direct sales in its AMPs? Only discovery will tell us. More to the point for liability purposes, even if Merck does not include direct sale prices in its

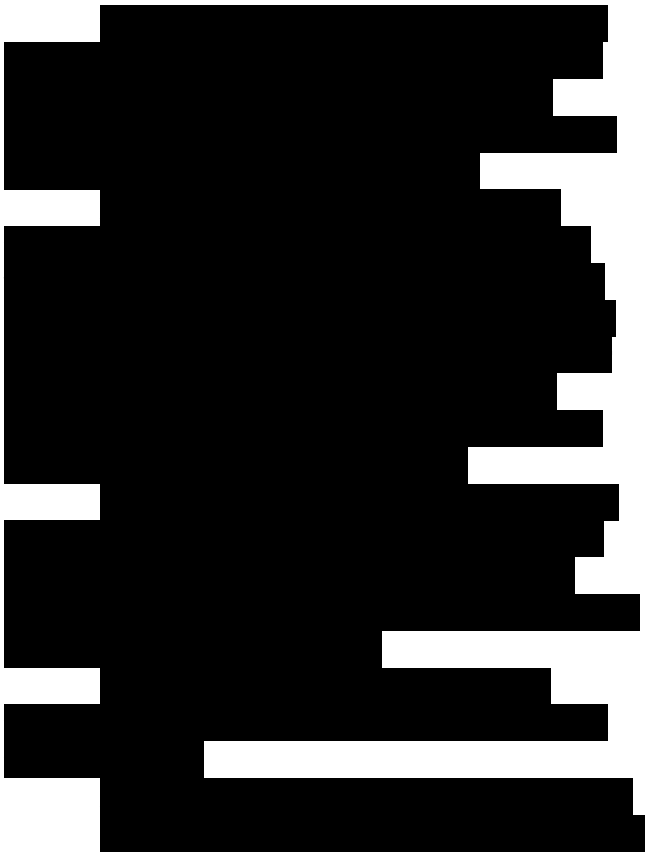
AMPs, what is Merck's true price to large direct customers, such as Costco, and how do those prices compare to the AWP Merck publishes?

Fourth, Merck's argument ignores the fact that manufacturers knowingly make sales through wholesalers where all discounts, rebates, prompt pay discounts and sometimes a portion of the prompt pay dating to the wholesaler are passed on to the end purchaser. Consider the following exchange with McKesson 30(b)(6) witness Leslie Morgan concerning sales to Wal-Mart's warehouse:



Morgan Depo. at 157:14-158:14 (Cicala Dec. Exh. A). Does Merck sell to Wal-Mart and other large customers at [redacted]? Are such sales included in Merck's calculation of AMP? More to the point for purposes of liability, what is Merck's true sales price in such contexts and how does that relate to the AWP Merck publishes? Only discovery will tell us.

Related is the issue of brokerage sales and the impact of same on Merck's calculation of AMP and, for liability purposes, Merck's net prices. Consider, for example, the following exchange with Cardinal Health 30(b)(6) witness Neil Warren concerning "Brokerage" sales through Cardinal to chain customers like Eckerd:



Deposition of Neil Warren (Cardinal Health) dated September 9, 2008 ("Warren 9/9/08 Depo.") at 162:3-163:3 (attached as Exhibit B to the Cicala Dec); *See also id.* at 180:9-181:8, 184:8-185:20 (testifying that Cardinal only got four (4) days float on Walgreens brokerage sales). Does Merck engage in this practice? And if so, are brokerage sales to retailers included in the Merck AMP? And, for liability purposes, what are those brokerage prices and how do they relate to the AWPs Merck published? Only discovery will tell us.

Fifth, Merck ignores that in the context of AMP, the Medicaid Rebate Agreement defines "wholesaler" as "any entity (including a pharmacy or chain of pharmacies) to which the labeler [manufacturer] sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug." *see* p. 11 to Exhibit 7 to the Declaration of Robert Funkhouser citing Medicaid Rebate Agreement section I(ee) [Dkt.No. 6574]. In other words, a "wholesaler" includes entities such as Costco and Eckerd (referenced in the deposition excerpts cited above) who purchase drugs directly from Merck and AMP is defined in manner that would permit Merck to include such direct sales in its calculation. Such direct sales to chain warehouses also may not result in a markup because there is no "middleman." But neither this nor Merck's true prices to such entities, nor how those true prices relate to Merck's published AWPs, can be known without discovery.

Sixth, what types of "providers" is Merck even referring to? Elsewhere in its opposition Merck makes the incorrect statement that the only relevant providers in this case are retail pharmacies. *See* Merck Opp. at 1, 13-14 [Dkt. No. 6572, Sub-dkt. No. 168]. But Merck knows –because it has the claims data- that NY Medicaid reimburses all providers of pharmacy and that means not only classic retail pharmacies but also LTC facilities, nursing homes, hospital outpatient pharmacies, clinics and others engaged in the practice of pharmacy.

Further confirming why discovery is needed, Merck tucks in a footnote that its AMPs '*may include* rebates to entities that are not reimbursed by Medicaid." ***May*** include? Does Merck not know if its AMPs include rebates to entities reimbursed by NY Medicaid? It knows what entities New York Medicaid reimbursed. That is contained within the NY claims data provided to defendants nearly one year ago (NYCO AWP 37223). Presumably, Merck also knows to whom it pays rebates. Regardless, Merck's phrasing makes plaintiffs' point: the

question of what Merck does or does not include in its AMPs and to whom Merck pays rebates and how those rebates impact Merck's net prices are all among the reasons discovery is required.

III. Merck's Criticisms of Mr. Devor Make No Sense and Fail Entirely

Merck argues that Mr. Devor's methodology is flawed because Mr. Devor did not weight his AMP/AWP spreads based on expenditure volume or transactions. What expenditure volume or transactions? In the context of the Schering motion for a protective order, Dr. Addanki used Schering's national sales and transactional data to weight averages among certain classes of trade. Such was not required, as explained below, but even if it were the exercise obviously cannot be engaged in without access to Merck's sales and transactional data (i.e. data which is among the very information sought by plaintiffs' motion).

Is Merck perhaps suggesting that Mr. Devor should have calculated spreads that somehow reflected New York Medicaid reimbursement expenditures? Such would make no sense since Merck's AMPs and AWPs are national figures and any spread-related weighting would have to be calculated based on national sales figures.

Is Merck's argument that their AMP/AWP spreads differ from state to state depending on how much a state spent in a particular year or quarter on Merck's drugs? There is no support for this proposition anywhere nor would it make any sense given that AMPs and AWPs are national numbers.

Regardless, it is prudent to revisit the origins of the 30% discovery screen. For purposes of limiting discovery, the Court initially determined (and the parties agreed through their joint presentation of CMO #33) that this 30% screen would be measured by two price points at issue in the Litigation.

> 2. (b) [Plaintiffs] shall allege a weighted average, or typical, price for each drug calculated on a reasonable good faith basis consistent with ¶5 of this Court's July 30, 2007 order and prior opinions.
>
> (c) any NDC for which the percentage difference between the weighted average, or typical, wholesale price alleged by plaintiffs and the published Average Wholesale Price ("AWP") for that NDC is 30% or less shall be moved from FACC Exhibit B-1 and placed in an amended FACC Exhibit B-2;
> (CMO 33, Sept. 14, 2007 [Docket No. 4745].)

Then, in the context of the Schering Motion for a Protective Order, the Court agreed with Schering that manufacturer-determined AMPs also could, for discovery purposes, essentially serve as the "weighted average or typical price for each drug calculated on a good faith basis". And it appears that Merck agrees with this proposition given that, as set forth above, Merck described AMP as a conservative check on the wholesaler data spreads in plaintiffs' complaint. *See* Merck Opp. at 2.

In any event, the Court thus ruled that manufacturer-determined AMPs and published AWPs represented two reasonable and appropriate measures through which spreads sufficient to trigger discovery obligations could be calculated. It was determined, specifically, that branded drugs with annual spreads between AMP and published AWPs of greater than 30% would be subject to discovery so that liability for the claims asserted could be evaluated. "A" hereto.

Now to this motion and the work of Mr. Devor. Undisputed is that at any given point in time, on any given day, there was, for the drugs at issue, (a) a published Merck AWP and (b) some "weighted average or typical price for each drug" (whether it be an AMP or an AAC based on wholesaler data as in plaintiffs' Rev. Exhibit B to the FACC). The difference between the two is the spread. It follows logically that an average of daily spreads can be used to arrive at a single, average spread for any particular year.

Mr. Devor calculated the spread between AMP and published AWP, for at-issue drugs, on every single day in every year at issue. The average spread over the year is based, therefore, on 365 inputs for that year – one for each day. The result is, by definition, a weighted and true average of the spread between AMP and published AWP at any given point in time during that year, as required. These average spreads are the foundation for Plaintiffs' motion. No order of the Court has ever called for any weighting of the ***spreads*** themselves based on transaction volume.

Defendants' argument, therefore that, "[f]ailing to consider transaction volume distorts the comparison between AMP and AWP because the former is a weighted figure and the latter is not" is entirely self-serving, flawed, and inconsistent with the purpose and requirements of the Court. The assertion speaks more to estimates of a measure of damages than to what is required to obtain the discovery needed to determine whether reported and published AWPs were inflated. At bottom, daily comparison between AMP and the published AWP is the most direct and appropriate manner in which to isolate the spread between these two numbers, and to isolate the amount by which reimbursement on each individual claim during a relevant timeframe may have been inflated. Only on a full record and after analysis of Merck's sales and transactional data can Merck's true prices be determined and compared to the AWPs which Merck published or caused to be published.

Merck also criticizes Mr. Devor for cherry-picking time periods. This argument likewise makes no sense. Mr. Devor has done exactly what the Court required and has presented annual spreads for all at-issue Merck drugs and NDCs. Plaintiffs seek discovery only on those with AMP/AWP spreads over 30% on an annual basis, as provided for by the Schering Order and consistent with CMO #33. Perhaps Merck is sensitive to cherry-picking since that is precisely

what it did when it had its expert prepare charts for this Court that purposefully omitted drugs on which the County Medicaid programs spent hundreds of millions of dollars and which, as Merck concedes, have over 30% spreads entitling plaintiffs to discovery. *See* Gaier Aff. Figure 3, *e.g.*

Merck argues that for the majority of the time, Merck's AMP to AWP spreads do not exceed 30%. *See* Merck Opp. at 16. This is another irrelevant point. Neither CMO #33 nor the September 2008 order required spreads that exceed 30% the majority of the time. CMO #33 has no temporal requirement and the September 2008 Order provides for discovery once spreads exceed 30% for the year. "A" hereto. Plaintiffs only seek compliance with that Order: they seek production of discovery for the drugs and NDCs for which the AMP/AWP spread exceeds 30% for the year.

IV. The Discovery Deadline is April 2010

Merck also attempts to distract from the issue at bar with discussions of timing of plaintiffs' discovery demands. Plaintiffs remind that the discovery cut off in this case is April 2010 and that plaintiffs' motion clearly has been filed well within that timeframe. Further, it is worth noting that the pleading challenges faced by plaintiffs here, by themselves, confirm how remarkably difficult it is for Medicaid to ascertain defendants' true prices or proxies for same. Even now, in the context of litigation and notwithstanding express direction from the Court, Merck still refuses to provide the information required for a full and fair adjudication of the claims leveled against it. Respectfully, Merck's obstructionism simply should not be permitted.

CONCLUSION

For all the foregoing reasons, plaintiffs' motion to compel discovery from Merck for the Drugs and NDCs with annual AMP/AWP spreads greater than 30% should be granted.

Dated: October 23, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Kathryn B. Allen, hereby certify that I caused a true and correct copy of the foregoing Reply Memorandum in Further Support of Plaintiffs' Motion to Compel Discovery from Defendant Merck & Co., Inc., to be served on counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: October 23, 2009

/s/ Kathryn B. Allen
Kathryn B. Allen